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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,766	06/27/2003	David Wynn	MCP-5014 NP	7412

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,766	WYNN ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *6,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The correction of claim 22 on 07/17/2006 in applicants arguments/remarks has been entered.

Election/Restrictions

The election of the following species has been considered: Active ingredient-ibuprofen, Soluble polymer- HPMCP, Insoluble polymer-CA. Claims 1-5,7-12 and 15-23 are readable on the elected species, claims 6 and 13-14 have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 recites the limitation "hydroxyalkylcellulose" in claim 9. There is insufficient antecedent basis for this limitation in the claim. To expedite the examining process the examiner replaced "claim 9" with claim 8 so it had proper antecedent basis and was searchable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5,7-12 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buehler et al. (US 6,432,442 B1, cited by applicant) in view of Roche (US 5,075,114, cited by applicant) in view of Wong et al. (5,532,244) and in further view of Dressman et al (US 5,789,393).

Buehler discloses a chewable pharmaceutical dosage form comprised by weight 1-20% gelatin, 10% hydrocolloid including HPC, up to 60% sweetener such as sorbitol and xylitol, the matrix further contains 2-30% of a taste masked coated pharmaceutically active agent including ibuprofen. See col 2 lin 40-56, col 3 lin 1-15, lin 43-col 4 lin 34 and claims. Incorporated by reference within Buehler is US 5,489,436 for its disclosed enteric coatings. 436' discloses the use taste masked coatings comprised by weight % of the total coating 5-95% cellulose acetate, an insoluble polymer and 5-95% dimethylaminoethyl methacrylate, a soluble polymer, the coating comprised 2-55% of the dry weight

of the coated particle. See abstr col 4 lin 49-56 and col 6 lin 54-59 in US 5,489,436. Regarding claim 20 whether or not the dosage form meets USP dissolution requirements was given no patentable weight by the examiner. Regarding claim 21 the limitation that the moisture content of not more than about 5 percent when dried at 105°C is considered ordinary experimental practice by the examiner and therefore it would have been obvious to dry the tablets to a certain moisture percentage to achieve the desired consistency. Buehler discloses that the water content can be as low as about 10%, which could fall within the range of about 5% depending on what the range of "about" meant.

Buehler does not disclose the exact water-soluble polymer HPMCP and Buehler is silent on the MW and viscosity in 2% aqueous solution of the HPC matrix.

Roche is used to primarily show that chewable tablets containing granules of enterically coated ibuprofen, coated by a blend of CA and hydroxypropyl cellulose, an obvious derivative of HPMCP, were well known at the time of the invention. See abstr.

Wong is only used to show that HPMCP an obvious derivative of HPC was well known at the time of the invention to be an enteric coating. Regarding claim 21 Wong discloses that the enteric coating can further comprise a pharmaceutically acceptable excipient such as polysorbate, which was used to prepare the enteric coating. See col 9 lin 34-48. The ratio in claim 22 of CA, HPMCP and polysorbate is considered met because: generally, differences in

concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Dressman is used only to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. See col 19 lin 65-col 20 lin 43.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Buehler discloses all that is encompassed within applicants claimed invention except the use of the exact water-soluble polymer HPMCP and the MW or viscosity in 2% aqueous solution of the HPC matrix, while Roche disclosed enteric coatings comprised of CA and a cellulose derivative, Wong disclosed the use of the specific cellulose derivative HPMCP for use in an enteric coating, which also comprised polysorbate and Dressmann was used to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. The motivation to combine the above

documents would be a chewable tablet comprised of an HPC matrix and a taste masked coating of ibuprofen, the coating comprised of CA, HPMCP and polysorbate. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER